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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/062,299

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Leroy E. Hood

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EXAMINER

SMITH, CAROLYN L

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/062,299	Applicant(s) HOOD ET AL.	
	Examiner Carolyn Smith	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) 1-21 and 36-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission, filed 8/14/08 and 10/15/08, have been entered.

Amended claims 22, 24, and 30, filed 8/14/08, are acknowledged. Claims 1-21 and 36-49 remain withdrawn as being drawn to non-elected subject matter.

Claims herein under examination are 22-35.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 22-35 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 22-35 are drawn to a process. A process is statutory subject matter under 35 U.S.C. 101 if: (1) it is tied to a particular machine or apparatus or (2) it transforms an article to a different state or thing (In re Bilski, 88 USPQ2d 1385 Fed. Cir. 2008).

The claimed subject matter is not limited to a particular apparatus or machine. To qualify as a statutory process, the claims should require use of a machine within the steps of the claimed

Art Unit: 1631

subject matter or require transformation of an article to a different state or thing. Insignificant extra-solution activity in the claimed subject matter will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. Preamble limitations that require the claimed process to comprise machine implemented steps will not be considered sufficient to convert a process that otherwise recites only mental steps into statutory subject matter. It is noted that the instant claim 22 recites “physically perturbing a component”; however, this is not a transformation of an article to a different state or thing. It is further noted that claims 22-35 do not explicitly require that the steps of the claimed method are performed on a machine. The applicants are cautioned against introduction of new matter in an amendment.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Stoughton et al. (P/N 6,132,969).

This rejection is maintained and reiterated for reasons of record.

Stoughton et al. disclose laboratory and computer methods for testing and confirming how well a network model represents a biological pathway in a biological system (abstract) wherein the biological pathway in a biological system represents a biochemical system. Stoughton et al. disclose obtaining measurements for drug and pathway responses (col. 52, lines 56-62) and perturbing and monitoring components in a network model (col. 53, lines 38-64) which represents physically perturbing a component, as stated in instant claim 22. Stoughton et al. disclose the network comprises logical operators relating to input cellular constituents (components), such as mRNA and proteins, to output classes of cellular constituents which are affected by the pathway (abstract), which represents assigning a cellular function to components (col. 10, line 61 to col. 11, line 3), as stated in instant claims 22, 24, and 30. Stoughton et al. disclose use of positionally addressable transcript microarrays which are ordered and reproducible matrices for easy comparison with each other and capable of containing single sites per specific mRNA (col. 45, lines 17-39, col. 46, lines 58-67, and col. 51, lines 39-49) and making measurements of graded drug exposure and of graded levels of modification/perturbation control parameters and other methods that statistically sample cDNA pools (col. 52, first and fourth paragraphs) and normalizing relative changes (col. 4, second and third paragraphs) wherein the microarrays inherently involve mRNA locations containing x and y dimensions (multidimensional coordinate points) representative of a data element of two or more components of a physically perturbed system comprising values for a data element for each of n components (i.e. measurements of drug exposure and levels of perturbation in a 2-dimensional microarray space) corresponding to the number of measured components within the biochemical system, as stated in instant claims 22, 24, and 30. Stoughton et al. disclose comparing measured

Art Unit: 1631

relative changes of each cellular constituent to defined relative changes (col. 4, second paragraph) and Figure 9 illustrates positioning “0” state over “1” state (col. 28, lines 3-22) which represents comparison to a reference region, as stated in instant claims 22, 24, and 30. Stoughton et al. disclose comparing relative changes in the biological system in response to perturbations of the network (abstract and col. 8, lines 40-41 and col. 8, line 64 to col. 9, line 12). Stoughton et al. disclose comparing relative changes between two states in a biological system (col. 3, lines 15-20) including normal reference “0” and perturbed expression “1” states (col. 7, lines 50-64 and col. 8, lines 34-52), which represents comparison to a reference expression region, as stated in instant claims 22, 24, 27, 30, and 33. Stoughton et al. disclose predicting how output classes behave in response to the chosen experiments by finding measures (multidimensional coordinate points) of relative change of cellular constituents (components) and finding goodnesses of fit (“the conformity between an experimental result and theoretical expectation”, according to Merriam-Webster’s online dictionary) of each observed component to an output class (reference data element region) based on strongest correlations (abstract), which represent a linkage to the perturbed biochemical network. Stoughton et al. disclose analyzing a scanned image by using an image grid program that creates a spreadsheet of the average hybridization at each wavelength at each site (col. 51, lines 1-5) which represents output. Stoughton et al. disclose the relative abundance of mRNA is scored as a perturbation if there is a difference of the two sources of mRNA tested (col. 51, lines 14-27) and outputting values of the network (abstract and col. 3, second and third paragraphs) which represents determining if the multidimensional coordinate point is within or outside the reference region and a difference (outside the region) is indication of linkage to a perturbation as well as providing an output, as stated in instant claims 22, 24, and

Art Unit: 1631

30. Stoughton et al. disclose assigning a cellular function to components of a network or pathway (col. 10, line 58 to col. 11, line 3), as stated in instant claims 22, 24, and 30. Stoughton et al. disclose determining the overall goodness of fit of the network model (network-associated expression region) from the individual goodnesses of fit of each observed component (abstract), which also represents determining the multidimensional coordinate point representing a data element of a set of components in a network, as stated in instant claim 24. Stoughton et al. disclose observing a system's response to known inputs via gene expression and/or protein abundances (col. 2, first paragraph), as stated in instant claims 23, 26, 28, 29, 32, 34, and 35. Stoughton et al. disclose the biological system as a cell, organism, and patient (col. 5, line 67 to col. 6, line 1) which represents the biochemical system, as stated in instant claims 25 and 31.

Thus, Stoughton et al. anticipate the limitations in claims 22-35.

Applicant summarizes amended claims 22, 24, and 30. Applicant argues that "x and y coordinates" of an array are locations of arrayed material such as mRNA on the array, and the physical location has no relationship to a data element. This argument is found unpersuasive as "data element" has been interpreted broadly and reasonably. Furthermore, Stoughton et al. disclose making measurements of graded drug exposure and of graded levels of modification/perturbation control parameters and other methods that statistically sample cDNA pools (col. 52, first and fourth paragraphs) and normalizing relative changes (col. 4, second and third paragraphs) of these spots which represent multidimensional coordinate points. Applicant argues that a data element is a value or analytical representation of factual information that describes a characteristic or a physicochemical property of a component of a biochemical

Art Unit: 1631

system, as stated in the specification (starting on page 28, line 26). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a value or analytical representation of factual information that describes a characteristic or a physicochemical property of a component of a biochemical system) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant summarizes the multidimensional coordinate point limitation in the instant claims and Figure 1 and argues they are different from the x and y coordinates of Stoughton et al. which do not represent values of a characteristic or property of a component. This statement is found unpersuasive as "multidimensional coordinate point" has been interpreted broadly and reasonably. Also, Stoughton et al. disclose making measurements of graded drug exposure and of graded levels of modification/perturbation control parameters and other methods that statistically sample cDNA pools (col. 52, first and fourth paragraphs) and normalizing relative changes (col. 4, second and third paragraphs) of these spots which represent multidimensional coordinate points. Applicant reiterate arguments which have already been found unpersuasive for reasons given above.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The

Art Unit: 1631

faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran, can be reached on (571) 272-0720.

January 2, 2009

/Carolyn Smith/
Primary Examiner
AU 1631